DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project:

Title: Child Care and Development Fund Tribal Plan Preprint.

OMB No.: New.

Description: The Child Care and Development Fund Plan Preprint serves as the agreement between the grantee (Indian Tribe or tribal organization) and the Federal government as to how the Block Grant programs will be operated. The plans provide assurances that the CCDF funds will be administered in conformance with legislative requirements, Federal regulations at 45 CFR parts 98 and 99 and other applicable instructions or guidelines issued by the Administration for Children and Families (ACF). The Tribal Plan Preprint (ACF Form 118A) is currently approved through 5/31/00 under the Plan Preprint approval for both State and Indian Tribes (OMB Approval Number 0970–0114). Since the tribal plan preprint must be revised to reflect the CCDF amended regulations (published 7/24/98 at 63 FR 39936–39998), it is being disaggregated from the State plan preprint approval. Therefore, a new collection and OMB control number is requested.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Plan Preprint	253	.5	35	4,427
CCDF Plan Amendments	253	.5	3	380

Estimated Total Annual Burden Hours: 4,807.

In compliance with the requirements of Section 3506(c)(2)(A) the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality,utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 15, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–33792 Filed 12–21–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 1999

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 1999. The Prescription Drug User Fee Act of 1992 (the PDUFA), as amended by the Food and Drug Administration Modernization Act of 1997 (the FDAMA), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Fees for applications for FY 1999 were set by the FDAMA, subject to adjustment for inflation. Total application fee revenues fluctuate with the number of fee-paying applications FDA receives. Fees for establishments and products are calculated so that total revenues from each category will approximate FDA's estimate of the revenues to be derived from applications.

FOR FURTHER INFORMATION CONTACT: Michael E. Roosevelt, Office of Financial Management (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5088.

SUPPLEMENTARY INFORMATION:

I. Background

The PDUFA (Pub. L. 102–571), as amended by the FDAMA (Pub. L. 105–115), establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)).

For 1998 through 2002, under the amendments enacted in the FDAMA, the application fee rates are set in the statute, but are to be adjusted annually for cumulative inflation since 1997. Total application fee revenues are structured to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases (workload adjustment).

For 1998 through 2002, FDA is required to set fee rates for establishment and product categories each year, so that the total fee revenue from each of these two categories are projected to be equal to the total revenue FDA expects to collect from application fees that year. This procedure continues the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fees--application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 1999 for application, establishment, and product fees. These fees are retroactive to October 1, 1998, and will remain in effect through September 30, 1999. For fees already paid on applications and supplements submitted on or after